James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF CLEMENT J. GRASSI, M.D.

(Assigned to the Honorable David G. Campbell)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

The plaintiffs' argument that Dr. Grassi is unqualified to "offer testimony reserved for FDA experts" is a strawman: Dr. Grassi is not offering regulatory opinions in this litigation.

The lone reference in Dr. Grassi's Rule 26 Report that even arguably comes close to the subject of the plaintiffs' Motion is Dr. Grassi's statement that he relies on the FDA's oversight of available products as part of his methodology in choosing medical devices for patients. But the plaintiffs have not challenged Dr. Grassi's methodology in arriving at the opinions expressed in his Rule 26 Report.

Rather, the entire basis of the plaintiffs' Motion is two snippets of factual deposition testimony based on Dr. Grassi's knowledge and experience. Neither bit of testimony reflects opinions "reserved for FDA experts," nor do they warrant a sweeping order that Dr. Grassi "be excluded from offering opinions related to the FDA standards, practices procedures, testing, processes, and/or the responsibilities of the Food and Drug Administration and its role in regulating and assuring the safety of IVC filters." (Mot. (Doc. 7326) at 4.)

For each of these reasons, the plaintiffs' Motion to Exclude Dr. Grassi's opinions should be denied.

I. ARGUMENT

A. Dr. Grassi's Rule 26 Report shows that he is not offering regulatory opinions.

Dr. Grassi's Rule 26 Report reflects that he is limiting his opinions to those within his purview of a practicing interventional radiologist who has researched, written about, and worked with IVC filters for several decades. (Dr. Grassi, Rule 26 Rep., Apr. 14, 2017.) The closest that Dr. Grassi comes to a "regulatory opinion" is in the description of his methodology in arriving at his opinions. He describes his methodology in this litigation in contrast to how the plaintiffs' experts formed their opinions. (Rule 26 Rep., Apr. 14, 2017, at 12, excerpt attached as Exhibit A.) Rather than relying on "summaries and analysis of individual and collections of spontaneous adverse event reports, testing

documents, Bard's internal e-mails and documents," Dr. Grassi noted that he has "not received this type of information for any product." (*Id.*). Rather, his methodology for treating patients with medical devices in his practice—the methodology by which he arrived at his opinions in this litigation—is to rely on the following sources information: "I rely on the FDA's oversight of available products, the peer-reviewed medical literature, the product's instructions for use document, any other information from the manufacturer that has been properly analyzed and considered, my experience with the products, my colleagues' experiences with the products, and the patient's individual medical condition." (*Id.*)

At trial, Bard intends to limit its questioning of Dr. Grassi to the issues addressed in his Rule 26 Report. And the plaintiffs have not challenged Dr. Grassi's methodology for arriving at the opinions contained in his Rule 26 Report. Accordingly, the plaintiffs' Motion should be denied as moot.

B. Neither of the two snippets of deposition testimony cited in the plaintiffs' Motion reflect opinions "reserved for FDA experts."

The plaintiffs' Motion is based entirely on two answers that Dr. Grassi gave during a five-hour deposition. First, counsel for the plaintiff asked Dr. Grassi for his opinion about the mechanisms by which IVC filters can fracture; and the evidence that Dr. Grassi is aware of that supports the mechanisms of fracture that he identified. (Dr. Grassi Dep. Tr., 95:7 to 97:10, June 15, 2017, excerpts attached as Exhibit B.) Although Dr. Grassi did not provide opinions in his Rule 26 Report about these issues, he responded that he knows from personal experience, through his testing the Simon Nitinol Filter as part of the 510(k) application for the filter, that manufacturers conduct bench testing that involves repetitive stress testing. (*Id.* at 96:14 to 97:10.)

Second, counsel for the plaintiff asked Dr. Grassi if counsel for Bard provided him with any information about whether and how Bard tested its filters to meet a durability standard. (*Id.* at 156:12-17.) Again, Dr. Grassi did not offer any opinions about this issue in his Rule 26 Report, but he responded that he is aware that Bard is required to undertake

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

bench testing of the filters as part of the 510(k) application process, which he believes includes benchtop and stress testing; and that, although he did not receive the test results from Bard, he relies on the FDA to evaluate the test results as part of the clearance of the device. (*Id.* at 156:19 to 157:19.)

Knowledge and experience are sufficient to qualify an expert under Rule 702. Thus, Dr. Grassi's first-hand knowledge that manufacturers, in fact, undertake bench testing of their filters is not "testimony reserved for FDA experts." (Mot. (Doc. 7326) at 4.) Yet the plaintiffs use the testimony to build a strawman that Dr. Grassi is unqualified to offer regulatory opinions, and that the Court should enter a broad order precluding Dr. Grassi from "offering opinions related to the FDA standards, practices, procedures, testing, processes, and/or the responsibilities of the Food and Drug Administration and its role in regulating and assuring the safety of IVC filters." (*Id.*) Unless and until the plaintiffs identify specific opinions in Dr. Grassi's Rule 26 Report that amount to FDA regulatory opinions outside of Dr. Grassi's knowledge, skill, experience, training, or education, the Court should deny the plaintiffs' motion as not ripe for consideration.

II. CONCLUSION

At trial, Dr. Grassi's opinions will be limited to the issues addressed in his Rule 26 Report, none of which are reserved for an FDA expert, and none of which the plaintiffs challenge in the instant Motion. Accordingly, the plaintiffs' Motion should be denied.

RESPECTFULLY SUBMITTED this 27th of September, 2017.

s/ Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Attorney for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000